

REMARKS

Upon entry of the foregoing amendment, claims 1-13, 17, 19-22, 24-52 and 59-62 have been canceled without prejudice and claims 14-16, 18, 23 and 53 have been amended.

Claims 14, 23 and 53 have been amended to clarify that the claimed nucleic acid consists of a DNA encoding a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:6.

Claims 15 and 16 have been amended to change “a nucleic acid” to read –the nucleic acid– in order to clarify that the nucleic acid recited in claims 15 and 16 is the same as that recited in claim 14.

The pending claims are 14-16, 18, 23 and 53-58.

The foregoing claim amendments should be entered because they greatly reduce the number of issues under consideration. In particular, the amendments are sufficient to obviate all the rejections under §§ 112, 102 and 103, as discussed in detail below. Moreover, Applicants submit that the foregoing amendments places the application in condition for allowance.

The § 112, First Paragraph, Rejection Should Be Withdrawn

The Office Action rejected claims 14-18, 23 and 53-62 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention. Applicants traverse this rejection.

As regards claims 59-62, Applicants have canceled these claims without prejudice, thereby rendering this rejection moot with respect to these claims.

As regards claims 14-16, 18, 23 and 53-58, Applicants submit that the foregoing amendment is sufficient to obviate the reasons stated for the § 112, first paragraph, rejection in the Office Action. In particular, the Office Action avers that the specification fails to sufficiently describe the genus of nucleic acids that hybridize, under moderately stringent conditions, to a nucleic acid encoding a polypeptide of SEQ ID NO:6. Although Applicants do not concede that this is the case, nonetheless claims 14, 23 and 53 have been amended to specify that the claimed nucleic acid consists of DNA encoding a polypeptide consisting of the amino acid sequence of SEQ ID NO:6. The claims thus no longer encompass nucleic acids that hybridize to a nucleic acid encoding SEQ ID NO:6 under moderately stringent conditions. Thus, Applicants submit that the amendment obviates the reasons stated in the Office Action for rejecting claims 14, 23 and 53 and the claims that depend on them under § 112, first paragraph.

With regard to claim 18, Applicants submit that the rejection under § 112, first paragraph, was improperly applied against this claim in the Office Action. The sole reason given in the Office Action for the rejection is that, allegedly, the specification fails to sufficiently describe the genus of nucleic acids that hybridize, under moderately stringent conditions, to a nucleic acid encoding a polypeptide of SEQ ID NO:6. However, claim 18, which was previously presented in the last response, specifically recites: “The isolated nucleic acid molecule of claim 14, said nucleic acid consisting of the sequence of SEQ ID NO:5” (emphasis added). Thus, claim 14 does not encompass a genus of nucleic acids that hybridize, under moderately stringent conditions, to a nucleic acid encoding a polypeptide of SEQ ID NO:6. Rather, claim 14 is limited to a specific nucleic acid that is identified by a specific SEQ ID NO. Therefore, Applicants submit that the § 112, first paragraph, rejection of claim 18 should be withdrawn, whether or not the foregoing amendment is entered.

The § 102 Rejections Should Be Withdrawn In View Of The Amendment

Claims 14-16 and 23 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Watanabe *et al.* Applicants submit that the foregoing amendment is sufficient to obviate this rejection.

Upon entry of the foregoing amendment, claims 14 and 23 have been amended to limit the recited nucleic acid to one that consists of DNA that encodes a polypeptide consisting of SEQ ID NO:6. The phrase “consisting of” indicates that the polypeptide encoded by the recited nucleic acid is limited to only those amino acids set forth in SEQ ID NO:6. In contrast, the Watanabe reference teaches a nucleic acid having many more nucleic acid residues than those that encode SEQ ID NO:6. As disclosed in the specification, SEQ ID NO:6 is a DD-domain polypeptide. Applicants are the first to have isolated and identified the DD-domain polypeptide of SEQ ID NO:6 and the nucleic acid encoding such DD-domain polypeptide. Nothing in the Watanabe reference teaches or suggests the existence of such a DD domain polypeptide. Nor does the Watanabe reference teach or suggest nucleic acids consisting of a DNA encoding a DD domain polypeptide. Accordingly, Applicants submit that the claims as amended are not anticipated by the Watanabe reference, and respectfully request withdrawal of this rejection.

Claims 14 and 23 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Scanlan et al. (US Patent No. 6,440,663). Applicants submit that this rejection has been obviated by the foregoing amendment.

Upon entry of the foregoing amendment, claims 14 and 23 have been amended as noted above. While the claims have been limited to a nucleic acid consisting of a DNA that encodes a polypeptide consisting of the amino acid of SEQ ID NO:6, Scanlan et al. provides no such

teaching. As described in the specification, SEQ ID NO:6 is a DD domain polypeptide. Applicants are the first to have isolated and identified the DD-domain polypeptide of SEQ ID NO:6 and the claimed nucleic acid encoding such DD-domain polypeptide. Nothing in the Scanlan et al. reference teaches or suggests the existence of a DD domain polypeptide. Nor does the Scanlan et al. reference teach or suggest nucleic acids consisting of a DNA encoding a DD domain polypeptide.

As noted in Applicants' previous response, the nucleic acid taught by Scanlan et al. reference is 833 bases long, whereas a nucleic acid consisting of a DNA encoding the polypeptide consisting of amino acid of SEQ ID NO:6 is 294 bases long. Moreover, the Scanlan et al. reference neither teaches nor suggests the existence of a separate DD domain peptide, such as that of SEQ ID NO:6. Rather, Scanlan et al. is concerned with antigens that are associated with renal cancer. As there is nothing in the Scanlan et al. reference to suggest making or isolating the specific nucleic acids recited in the present claims, Applicants submit that the claims as amended are not anticipated by this reference, and request withdrawal of this ground of rejection.

The § 103(a) Rejection Should Be Withdrawn In View Of The Amendment

Claims 53 and 55-58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Watanabe, Scanlan and Matthews. Applicants traverse this ground of rejection as follows.

In order to render a claim obvious, a combination of references must teach each element of the claim to one of ordinary skill in the

Upon entry of the foregoing amendment, claim 53 has been amended to recite a nucleic acid molecule consisting of a label linked to DNA consisting of a DNA encoding a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:6. As discussed in detail above, neither Watanabe nor Scanlan teaches a nucleic acid consisting of a DNA encoding a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:6. Although Matthews et al. may teach a variety of analytical strategies for the use of DNA probes, the reference fails to make up for the deficiency in both Watanabe and Scanlan that they fail to teach or suggest a DNA encoding a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:6. As each of claims 55-58 depends ultimately from claim 53, these arguments apply equally to them.

As the combination of Watanabe, Scanlan and Matthews fail to provide teaching or suggestion of each limitation of the claims, the rejection under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

The § 112, First paragraph Rejection Of Claims 59-62 Is Moot

Claims 59-62 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by the written description. While not conceding the propriety of this rejection, Applicants have canceled claims 59-62, thus rendering this rejection moot.

CONCLUSION

Applicants submit that the foregoing amendments and remarks are fully responsive to the outstanding office action and are sufficient to render claims 14-16, 18, 23 and 53-58 allowable.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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